

**REMARKS**

**I. Status of the Claims**

Applicants respectfully thank the Examiner for his withdrawal of the finality of the previous Office Action and his issuance of a new Office Action. Further, Applicants respectfully thank the Examiner for the rejoining of previously withdrawn claims 9, 11, 13 and 14.

Claims 1-5, 8, 9, 11, 13 and 14 are pending in this case. The Examiner has indicated that claims 1-5, 9, 11, 13 and 14 are allowed. Claim 8 has been cancelled without disclaimer or prejudice. Applicants reserve the right to pursue the subject matter encompassed by all canceled claims in one or more divisional or continuation applications.

**II. Summary of Examiner Interview**

Applicants' representative contacted the Examiner on January 27, 2005, and again on February 1, 2005, to discuss the Examiner's rejection of claims 6-8 in the August 25, 2004, Office Action. Although the Examiner did not include a summary of the interviews in the present Office Action, Applicants note the following. On January 27, 2005, the Examiner requested the cancellation of claims 6 and 7 and the amendment of claim 8 such that the abbreviations found in the claim be enclosed within parentheses. Applicants suggested further amending claim 8, such that it depend from claim 1. The Examiner indicated that doing so would put the application in condition for allowance. Applicants filed a written Communication on January 31, 2005, in which claims 6 and 7 were cancelled and claim 8 was amended as per the Examiner's request in the January 27, 2005, interview.

On February 1, 2005, the Examiner contacted Applicants' representative and requested that amended claim 8 be rewritten to eliminate the use of Markush language and indicated that a new Office Action would be issued based on Applicants improper incorporation by reference of foreign patents.

### **III. Rejection Under 35 U.S.C. § 112, First Paragraph: Enablement**

The Examiner rejected claim 8 under 35 U.S.C. § 112, first paragraph. The rejection states that "the specification, while being enabling for the pharmaceutical combination comprising one or more compounds of claim 1 and 3-hydroxy-3-methylglutaryl Coenzyme A, cholesterol absorption inhibitors and insulin does not provide enablement for all of the other compounds or class of compounds recited in claim 8." Office Action, at 4. Specifically, the Examiner asserts that Applicants' specification does not enable one of ordinary skill in the art to make or use the claimed invention by noting (1) the limited amount of direction provided by the inventors in combination with (2) the lack of working examples and (3) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *Id.* at pages 4-6. Applicants disagree for at least the following reasons.

According to the C.C.P.A., an applicant's specification is presumptively enabled for the full scope of the claims. *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971) (emphasis added); accord, M.P.E.P. § 2164.04. In fact, "[a]s a matter of Patent Office practice . . . [a specification] must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements." *In re Armbruster*, 185 U.S.P.Q. 152, 153 (C.C.P.A. 1975) (emphasis added).

The test of enablement is whether one of ordinary skill in the art could make the invention from the disclosure in the patent coupled with information known in the art without undue experimentation. M.P.E.P. § 2164.01. To determine whether experimentation is undue, the Examiner must apply the eight factors identified in the Federal Circuit's decision in *In re Wands*, 8 U.S.P.Q.2d. 1400, 1404 (Fed. Cir. 1988). M.P.E.P. § 2164.01(a).

The M.P.E.P. specifically states that the Examiner has the initial burden to establish a reasonable basis to question the enablement of the claimed invention. M.P.E.P. § 2164.04. This reasonable basis may be established by the Examiner by "making specific findings of fact, supported by evidence, and then drawing conclusions based on these findings of fact". . . "[h]owever, specific technical reasons are always required." *Id.* (emphasis added). Absent such evidence, the burden does not shift to the Applicants. *In re Marzocchi*, 169 U.S.P.Q. at 369.

In the present case, the Examiner has failed present such evidence and has also failed to indicate that Applicants must disclose more than they have. Instead, the Examiner has provided a general discussion of the aforementioned *Wands* factors which includes broad rationales and support for the current rejections. Office Action at page 4-6. Accordingly, until the Examiner provides evidence, i.e., specific technical reasons, showing that one of ordinary skill in the art would need more information, a *prima facie* case has not been established. M.P.E.P. § 2164.04.

In his rejection, the Examiner asserts that due to the unpredictability of the art, Applicants have not provided enough guidance to allow a skilled artisan to make and use the present invention "as instantly claimed." Office Action, at 5. First, the Examiner

has failed to provide evidence showing that Applicants' disclosure is insufficient in view of the knowledge of one of ordinary skill in the art. Applicants' generic teaching, coupled with the included examples, provides one of ordinary skill in the art with the necessary direction to apply well-known principles of chemical synthesis to arrive at Applicants' compounds claimed in claim 8. Indeed, Applicants note that under the law, the scope of enablement is more than what is disclosed in Applicants' specification; it is also the scope of what would be known to one of ordinary skill in the art. *National Recovery Technologies Inc. v. Magnetic Separation Systems Inc.*, 49 U.S.P.Q.2d 1671,1676 (Fed. Cir. 1999). Moreover, the Examiner has previously acknowledged that the artisans in the field of the invention possess an extremely high level of skill.<sup>1</sup> Therefore, given the rule that what is well-known in the art is best omitted from a specification, coupled with the highly skilled artisans in this field, Applicants' specification likely provides more than what is required for an enabling disclosure. See M.P.E.P. §2164.08.

The Examiner also asserts a lack of working examples and guidance in the specification "for making and using combinations of one or more compounds of claim 1 with representative examples of compounds belonging to non-diabetic related classes as recited in claim 8." Office Action, at 6.

Applicants are surprised by such an unsupported assertion. Applicants specifically provide working examples on page 17, line 13 through page 63, line 19, that

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<sup>1</sup> "The skilled artisan in this field is that of an MD for therapeutic administration and/or a Ph.D. skilled in the development of therapeutics." Final Office Action mailed April 16, 2004, at 6.

are enabling for pharmaceutical combinations comprising one or more compounds of claim 1 and all of the compounds or class of compounds recited in claim 8.

Furthermore, pages 8-13 of the present specification provide examples by which the pharmaceutical compositions claimed in claim 8 are synthesized and utilized.

Unquestionably, one of ordinary skill in the art could follow the teachings of the specification and the included examples to make and use the invention claimed in claim 8. Moreover, Applicants respectfully remind the Examiner that the enablement requirement of 35 U.S.C. § 112, first paragraph, does not require working examples. *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984) (explaining that prophetic examples “does not automatically make a patent non-enabling”); *In re Long*, 368 F.2d 892, 895 (C.C.P.A. 1966) (stating that “[t]he absence of a working example, denominated as such, does not compel the conclusion that a specification does not satisfy the requirements of 35 U.S.C. 112”); and M.P.E.P. § 2164.02 (“[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be ‘working’ or ‘prophetic.’”).

Applicants assert that, given the detail of the specification and examples, one of ordinary skill in the art would have more than sufficient information to prepare the compounds claimed in claim 8 and would not, as asserted by the Examiner, have to resort to undue experimentation. Thus, in contrast to the statements on pages 5 and 6 of the Office Action, the present specification provides a large amount of direction by the inventors, as well as numerous examples.

Accordingly, a proper analysis of the *Wands* factors necessarily leads to the conclusion that the present specification shows how to make and use the claimed invention without undue experimentation, and Applicants respectfully request withdrawal of this rejection under § 112, first paragraph

However, although we do not agree with the Examiner's rejection of claim 8, solely for the purpose of advancing prosecution of this application, Applicants have cancelled claim 8. Applicants respectfully assert that this amendment places the current application in condition for allowance.

#### **IV. Objection to the Specification**

The Examiner requires that the specification be amended to recite the contents of foreign priority documents, which are incorporated by reference into the present specification. Office Action, at 2. The Examiner states that such incorporation of "essential material" into the specification of the present application by reference to foreign patents is "improper." *Id.* Specifically, the Examiner asserts that Applicants' disclosure is objected to because Applicants "attempt to incorporate subject matter into this application by reference to WO 98/08871, WO 9903861, [and] WO 97/41097" for certain claimed compounds. *Id.*, at 2-3.

In the interest of advancing prosecution, the specification has been amended. Specifically, reference to WO 98/08871, WO 99/03861 and WO 97/41097 have been deleted and replaced with reference to the corresponding U.S. Patent Nos. 6,268,343; 5,889,002; and 6,225,310, respectively, all of which were filed and issued prior to the filing date of the present application. Applicants' representative attests that the amendatory references contain the same material originally incorporated by reference in

the foreign references and, therefore, no new matter has been added by amending the specification as such. See M.P.E.P. § 608.01(p)(I)(A)(2). Therefore, these objections are now moot and the application is in condition for allowance.

#### **IV. Conclusion**

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: April 27, 2005

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